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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,185	02/25/2002	Thomas Dag Horn	023533-0144	4869

7590 05/31/2005

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,185	HORN ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,15,33,36,37 and 48-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,15,33,36,37 and 48-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/7/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.6.0

Re: Horn *et al.*

Date of priority: 06/25/1999

Request for Continued Examination

The request filed on 03-07-2005 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/081185 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 1, 4-7, 15, 33, 36-37, and 48-51 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

In the remarks filed 03-07-2005, page 6, applicants remind the Examiner that should any linking claims be allowed, the restriction requirement must be withdrawn. Applicants argue that if claim 1 is found allowable, the restriction requirement under which the Examiner has withdrawn Claim 9 and the other species claims encompassed by the genus claim 1 must be withdrawn, and the species claims considered. These arguments have been carefully considered but are not found relevant. Claim 9 was withdrawn because it did not read on applicant's elected invention, drawn solely to bacterial and candida antigens. Further, the original restriction requirement did not restrict nor identify claim 1 as a genus claim nor did the requirement indicate

the presence of any species linked to the genus. Thus, even if Claim 1 is found allowable, the restriction requirement cannot not be lifted because there are no linking claims. Only those claims drawn to the original independent and distinct invention can be found allowable. Thus, applicant's arguments have not been found persuasive.

Rejections Maintained:

Claims 1, 4-7, 33, and 36 remain rejected and new claims 48-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Bostwick, E. (US2002/0009429 A1, January 29, 1999) for the reasons of record and for the reasons set forth below.

Applicants newly argue (Remarks, page 7) that the Examiner erred in ruling that the Inventor's Declaration (filed 11-19-2004) was ineffective in overcoming the Bostwick reference and that the declaration "shows possession" of the invention before the filing date of Bostwick. Subsequently, in contrast, applicants appear to concede that while the Declaration does not establish possession of a pharmaceutical composition comprising bacterial and candida antigens, the requirement does not mean that the affiant must show a reduction to practice of every embodiment of the invention. This argument has been considered but is not found persuasive because it is not clear how applicants can argue a reduction to practice for embodiments that are not claimed. The currently claimed invention is only drawn to bacterial and candida antigen for which the Declaration did not establish possession of nor a reduction to practice with prior to the date of the Bostwick reference.

Applicants further argue (pages 7-8) that the facts in this case parallel the ruling of *In re Stryker* in which the CCPA overturned the BPA with regards to the Board's application of *Tanczyn*. This argument has been considered but is not found persuasive as the facts in this case do not parallel the decision made by the CCPA regarding *In re Stryker*. The CCPA overruled the Board because they erred in applying *Tanczyn*. That is not the case here. *Tanczyn* was appropriately applied because the Inventor's Declaration did not contain facts showing a completion of the invention commensurate with the extent of the invention claimed, i.e. the declaration did not provide evidence of possession of the bacterial and candida antigens. In contrast, Strkyer's declaration professed to have met the weight percentages, but contained no "corroborating evidence" showing those weight percentage limitations. The CCPA held that an antedating affidavit is sufficient where it alleges conception and reduction to practice of a claimed process even when there is no corroborating evidence showing specific limitations. In contrast, the dispute here does not involve a specific process nor any specific limitations or percentages or ranges. Rather the claims are drawn to two specific products for which applicant has neither shown possession of nor a reduction to practice.

On the other hand, applicants argue that Declaration establishes possession of the "originally" filed claim 1--- a pharmaceutical composition comprising at least two antigens. Applicants argue that the broader filed original claim would enjoy the embodiments shown by Dr. Horn's declaration, and it "cannot be law" that the Examiner can demand that the claims be narrowed to make searching easier, and then assert that the Applicants showing of possession with a Rule 131 Declaration is not sufficient with the narrow claims. This argument has been considered but is not found persuasive. On the contrary, the examiner is allowed by law to

restrict the inventions into patentably distinct groups. Under the statute an application may properly be restricted when the inventions have been shown to be independent or distinct and when there exists a serious burden on the examiner. Hence, since the inventions were properly restricted (Action mailed 04-09-2004) and the restriction was made FINAL (Action mailed 07-26-2004), the fact that Applicants Declaration would have been sufficient to remove the prior art with the original claims intact is irrelevant.

Alternatively, applicants argue (Remarks, bottom of page 8) that evidence of a reduction to practice of the unclaimed mumps and candida antigen establishes possession of the claimed "bacterial" and candida antigens because "the latter composition is obvious in view of the former". Applicants refer to the decision held in *in Re Spiller* in which the CCPA held that appellant has shown a reduction to practice of his basic invention, which showing will also suffice as to claims differing therefrom only in details which are obvious to one of ordinary skill in the art. Hence, Applicants argue that it would have been obvious to one of ordinary skill in the art, in view of Applicants' invention of using mumps antigen and candida antigen to treat warts, that any antigen which induces or is capable of inducing a delayed type hypersensitivity response could be used to treat warts. These arguments have been carefully considered but are not found persuasive because it would appear that the obviousness only applies to possession when the claimed invention carries with it certain readily known variations and adaptations. In this case, there is insufficient evidence to suggest that every antigen in the world that induces a cutaneous delayed type hypersensitivity would predictably substitute for the mumps and candida antigens. Thus, applicant's arguments have not been found persuasive, and the rejection is maintained.

Claims 1, 4-7, 33, 36-37 remain rejected and new claims 48-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Clements, J. (US Patent No. 6,033,673, March 18, 1998) for the reasons of record and for the reasons set forth below.

Applicants argue (pages 10-16) that the Examiner merely asserted without evidence and without providing any reasoning that the E. coli heat-labile enterotoxin mutant LT(R192G/L21 1A) is an antigen and induces a cutaneous DTH response, and that therefore the composition of the mutant enterotoxin and a candida antigen suggested in Clements anticipates the present claims. Applicants appear to broadly argue that the Office erred in shifting the burden to the Applicant to prove that the claimed composition was not anticipated because the use of *In Re Best* and *Ex parte Gray* are unrelated to the present situation. Applicants argue (page 12) that both decisions concerned products that were nearly identical to the prior art products known to the inventors, but were prepared by a new process. Where the only difference between a claimed product and a prior art product is the way it is produced, the board in *Ex parte Gray* and the court in *In re Best* have held that it is appropriate to shift the burden to the Applicant to demonstrate that the different method of production creates a patentable difference in the product. Thus, since the present claims are not product-by-process claims, Applicants argue that the lesser standard is not appropriate. These arguments have been carefully considered but are not found persuasive. There is no *per se* rule that the rejected claims must be product-by-process claims in order to apply the decisions of *in Re Best* or *Ex parte Gray*. For example, MPEP 2112 refers to *in Re Best* to explain that something which is old does not become patentable upon the discovery of a new property; "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562

F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)". This applies in the instant case because the claims are broadly drawn to a pharmaceutical composition comprising any bacterial antigen (and candida antigen). And, since the prior art clearly teaches said pharmaceutical composition, any assertions of specific functional properties attributed to the antigens are merely inherent and do not necessarily make the claim patentable. Applicants further argue (page 13-14) that the Examiner has provided no evidence or rationale for the conclusion that the prior art's teaching of the bacterial antigen is capable of producing a DTH response. Applicants argue that nothing in the prior art "indicates that the mutant enterotoxin induces any immune response against itself, much less a cutaneous DTH immune response. These arguments have been carefully considered but are not found persuasive. First, the specification does not limit the type of bacterial antigen to be used in the pharmaceutical composition. The specification only teaches (para 27) that the antigens useful in the present invention can be of viral, fungal or bacterial origin. Secondly, claims must be interpreted as broadly as their terms reasonably allow. Thus, in view that the specification teaches that any antigen of bacterial origin is preferred, the teachings of the prior art and the issues of inherency apply. Moreover, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Applicants further argue (page 14) that not all antigens induce DTH responses. In particular, Applicants argue (page 15) that Clements discloses compositions containing a mutant enterotoxin and an antigen, and that administration of these compositions induces an immune

response to the antigen (col. 9, lines 36-41). However, applicants argue that Clements does not disclose that any immune response directed to the mutant enterotoxin is generated or that DTH response to the bacterial antigen is generated. Applicants argue that since not all antigens in all compositions induce a DTH response, and because Clements does not disclose that any DTH response to the mutant enterotoxin of its compositions is generated, it is therefore not a necessarily inherent characteristic of the composition. This argument has been considered but is not found persuasive. The fact that some antigens vary in their type of immune responses does not represent explicit evidence to the contrary, i.e. that the prior art antigen is incapable of inducing a DTH. Also, the arguments of counsel cannot take the place of evidence in the record. In re Schulze,346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. In this particular case, it would appear that applicants are arguing that the prior art enterotoxin is incapable of inducing a cutaneous DTH.

Applicants further argue (page 15) that even if the mutant enterotoxin of Clements were inherently an antigen that is capable of inducing a DTH, new claims 48-51 are still novel over Clements. Applicants argue that since the bacterial antigen of Clements is a new engineered molecule generated by site-directed mutagenesis, no human or other mammal has been exposed to it and no human or other mammal would be expected to have a preexisting sensitivity to it. This argument has been considered but is not found persuasive. On the contrary, Clements

teaches that the pharmaceutical composition comprising the enterotoxin and the effective antigen may be administered as boosters wherein the initial administration of the toxin and antigen is followed by a boost which may comprise the antigen alone or in combination with the enterotoxin (column 9, lines 50-65). Hence, the prior art anticipates prior exposure and thus preexisting sensitivity to each of said antigens prior to the administration of the boost. With regards to claim 50, applicants argue that since enterotoxin adjuvant of the prior art is a novel engineered molecule, "it is not likely that humans or other mammals have a high prevalence of reactivity to it". This argument has been considered but is not found persuasive for the reasons set forth above. Thus, applicant's arguments have not been found persuasive, and the rejection is maintained.

Claims 1, 4-7, 15, 33, 36-37 remain rejected and new claims 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clements, J. (US Patent No. 6,033,673, March 18, 1998) or Bostwick, E. (US2002/0009429 A1, January 29, 1999) in further view of the CANDIN® package insert text, IDS, Reference A12, submitted March 14, 2003.

Applicants erroneously argue that Bostwick is removed as prior art. Separately, applicants reiterate that the teachings of Clements do not disclose that the enterotoxin induces or is capable of inducing a cutaneous DTH. Applicants add that the CANDIN package insert does nothing to remedy these deficiencies. These arguments have been carefully considered but are not found persuasive for the reasons of record. Further, Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be

considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus, applicant's arguments have not been found persuasive, and the rejection is maintained.

No claim is allowed.

Conclusion

This is a continutaion of applicant's earlier Application No. 10/081185. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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